UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/626,007	07/24/2003	Robert Ginsburg	RADNT-008G3	9911

7590 04/04/2005

Robert D. Buyan
STOUT, UXA, BUYAN & MULLINS, LLP
Suite #310
4 Venture
Irvine, CA 92618

EXAMINER	
NASSER, ROBERT L	
ART UNIT	**PAPER NUMBER**
3736	

DATE MAILED: 04/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/626,007	GINSBURG ET AL.
	Examiner	Art Unit
	Robert L. Nasser	3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 November 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *50-84 and 88-94* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *50-84 and 88-94* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 64-84 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-24 of U.S. Patent No. 6527798 in view of Saab 5624392. The patenteds claim lack the helical flow path. Saab shows such a flow path 6. As such, it would have been obvious to modify the prior invention to use such a helical flow path, as it is merely the substitution of one known balloon heat exchanger for another.

Claims 88-94 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 25-30 of U.S. Patent No. 6527798 in view of Panyard et al. Panyard showed a thermal control system that allowed the user to set a desired target temperature and sensed body temperature to control the supply of fluid relative to the target temperature. While the system of Panyard is not a catheter, it is a heating/cooling system and the supply system was identical to that of the previous invention. From this teaching, it would have been obvious to modify the previous invention to use such a control system to ensure precise

control of the patient's condition. In addition, applicant has not stated that the shape of the balloon is for a particular purpose or that it solves a stated problem. As such, the shape of the balloon would have been a mere matter of design choice for one skilled in the art.

Claims 88-94 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-68 of U.S. Patent No. 6635076. The patented claims lack the helical balloon. In addition, applicant has not stated that the shape of the balloon is for a particular purpose or that it solves a stated problem. As such, the shape of the balloon would have been a mere matter of design choice for one skilled in the art.

Claim Objections

Climas 50-93 and 88-94 are objected to in that the drawings fail to show all of the features of the claims. Specifically, figure 20 shows a balloon with a helical flow path, but not a helical balloon or helical lobe of a balloon.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 50-57, 60, and 62 are rejected under 35 U.S.C. 102(b) as being anticipated by Saab 5624392. Saab shows a heat exchange catheter system including an elongate flexible catheter having a proximal and distal end, where the catheter has a distal insertion portion including balloon 72 or 236. It does not show a helical balloon or a balloon with a helical lobe. However, applicant has not stated that the shape of the balloon is for a particular purpose or that it solves a stated problem. As such, the shape of the balloon would have been a mere matter of design choice for one skilled in the art. The device further has a working lumen 11, which contains a guidewire therein (see column 8, lines 3-4). There is a fluid circulated through the balloon the effect heat exchange. With respect to claim 51, the balloon of figure 7 has a plurality of lobes. With respect to claim 57, 60, and 62 in column 14, lines 61-67, Saab teaches using the device to deliver medication or a medical device including a therapeutic device. As such, it is inherent that there be a device for infusing the medicine.

Claims 58, 59, 61, and 63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saab. Applicant has not selected the specific devices listed for a specific reason and applicant has not stated that their selection solves a stated problem. Therefore, the exact medical device used with Saab's device would have been a mere matter of design choice for one skilled in the art.

Claims 88-92 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saab 5624392 in view of Panyard 5755755. Saab does not teach the recited control system. Panyard showed a thermal control system that allowed the user to set a desired target temperature and sensed body temperature to control the supply of fluid

relative to the target temperature. While the system of Panyard is not a catheter, it is a heating/cooling system and the supply system was identical to that of Saab. From this teaching, it would have been obvious to modify Saab to use such a control system to ensure precise control of the patient's condition. In addition, applicant has not stated that the shape of the balloon is for a particular purpose or that it solves a stated problem. As such, the shape of the balloon would have been a mere matter of design choice for one skilled in the art.

Claims 64-84 would be allowable if the double patenting rejection were overcome. Claims 64-84 define over the art, in that none of the art shows the blood flow channeling sleeve, as recite in that claim. The examiner notes that tubes 244 or 246 of Saab might be considered a channeling sleeve, but they are closed at one end and therefore not capable of channeling blood.

Claims 93 and 94 would be allowable if the double patenting rejection were overcome and if rewritten to include all of the limitations of the base claim and any intervening claims paragraph. Claims 93-94 define over the art in that none of the art shows a plurality of catheter devices, in combination with claim 88, as claimed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Fogarty 4762130 shows a catheter with a helical balloon.

Applicant's arguments filed 11/2/004 have been fully considered but they are moot in view of the new grounds of rejection.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert L. Nasser whose telephone number is (571) 272-4731. The examiner can normally be reached on Mon-Fri, variable hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert L. Nasser
Primary Examiner
Art Unit 3736

RLN
March 29, 2005

ROBERT L. NASSER
PRIMARY EXAMINER